

Claim Amendments

Appendix A

1. (Currently amended) ~~Oral~~ An oral dosage form for proton pump antagonists (APA) comprising an effective amount of a proton pump antagonist, or a pharmacologically acceptable solvate, hydrate or salt thereof, together with one or more excipients, where the proton pump antagonist or the pharmacologically acceptable solvate, hydrate or salt thereof is stabilized in the dosage form by one or more basic excipients.

2. (Currently amended) ~~Dosage~~ The dosage form according to Claim 1, wherein the basic excipient is present in finely divided form and thoroughly mixed with the proton pump antagonist, or the pharmacologically acceptable solvate, hydrate or salt thereof.

3. (Currently amended) ~~Dosage~~ The dosage form according to Claim 1 [[or 2]], characterized in that one or more excipients which, on oral intake of the dosage form, bring about rapid disintegration of the dosage form are

~~present, and, where appropriate, further excipients, are additionally present.~~

4. (Currently amended) ~~Dosage~~ The dosage form according to Claim 1 ~~[[to 3]]~~, characterized in that the dosage form is selected from the group consisting of tablets, coated tablets, pellets, microtablets in capsules and granules in capsules.

5. (Currently amended) ~~Dosage~~ The dosage form according to Claim 4, characterized in that it comprises coated tablets.

6. (Currently amended) ~~Dosage~~ The dosage form according to Claim 3, characterized in that it comprises a rapidly disintegrating dosage form with immediate release of the active ingredient ~~(immediate release solid oral dosage form)~~.

7. (Currently amended) ~~Dosage~~ The dosage form according to Claim 3, characterized in that it comprises a rapidly disintegrating dosage form with immediate release of the active ingredient ~~(immediate release solid oral dosage~~

~~form~~), and wherein the dosage form shows a disintegration of not more than 5 minutes under the test conditions described for ~~"Dispersible Tablets"~~ "Dispersible Tablets" in the European Pharmacopoeia 4<sup>th</sup> edition.

8. (Currently amended) ~~Dosage~~ The dosage form according to Claim 3, characterized in that it comprises a rapidly disintegrating dosage form with immediate release of the active ingredient ~~(immediate release solid oral dosage form)~~, and wherein the dosage form shows a disintegration within 3 minutes under the test conditions described for ~~"Dispersible Tablets"~~ "Dispersible Tablets" in the European Pharmacopoeia 4<sup>th</sup> edition.

9. (Currently amended) ~~Dosage~~ The dosage form according to Claim 7, characterized that it shows a release of the active ingredient of greater than or equal to 85% after 15 minutes in 0.1 N ~~hydrochloric~~ hydrochloric acid.

10. (Currently amended) ~~Dosage~~ The dosage form according to Claim 3, characterized in that one or more substances selected from the group consisting of fillers and

disintegrants are present as excipients which bring about rapid disintegration of the tablet.

11. (Currently amended) ~~Dosage~~ The dosage form according to Claim 10, characterized in that at least one filler and at least one disintegrant are present.

12. (Currently amended) ~~Dosage~~ The dosage form according to Claim 11, characterized in that microcrystalline cellulose is present.

13. (Currently amended) ~~Dosage~~ The dosage form according to Claim 1 ~~[[to 3]]~~, characterized in that one or more further excipients selected from the group consisting of lubricants, aromas, ~~colouring~~ coloring agents, ~~flavourings~~ flavorings and surface-active substances are present.

14. (Currently amended) ~~Dosage~~ The dosage form according to Claim 1, characterized in that the basic excipient is selected from the group consisting of sodium carbonate, calcium carbonate, magnesium carbonates, magnesium oxide, magnesium hydroxide, magnesium metasilicate aluminate,

magnesium silicates, magnesium aluminate, synthetic hydrotalcite (~~synthetic~~), aluminium magnesium hydroxide, [[and]] calcium hydroxide, basic salts of amino acids, sodium hydroxide, trihydroxymethylaminomethane, trisodium citrate, disodium hydrogen phosphate, [[and]] trisodium phosphate [[or]] and mixtures thereof.

15. (Currently amended) ~~Dosage~~ The dosage form according to Claim 14, characterized in that the basic excipient is sodium carbonate ~~is involved~~.

16. (Currently amended) ~~Dosage~~ The dosage form according to Claim 14, characterized in that the basic excipient is disodium hydrogen phosphate, trisodium phosphate or a buffer ~~systems composed of~~ system comprising disodium hydrogen phosphate and sodium hydroxide ~~are involved~~.

17. (Currently amended) ~~Dosage~~ The dosage form according to Claim 1, ~~characterized in that a compound~~ wherein the proton pump antagonist (APA) is selected from the group consisting of AU-461, soraprazan (BYK61359), DBM-819, KR-60436, T-330, YH-1885, YJA-20379-8 and 2,3-dimethyl-8-(2-ethyl-6-methylbenzylamino)imidazo[1,2-a]pyridine-6-

carboxamide ~~is present as reversible proton pump~~  
~~inhibitor.~~

18. (Currently amended) ~~Dosage~~ The dosage form according to Claim 17, characterized in that (7R,8R,9R)-2,3-dimethyl-8-hydroxy-7-(2-methoxyethoxy)-9-phenyl-7,8,9,10-tetrahydroimidazo[1,2-h][1,7]naphthyridine (INN soraprazan) or a pharmacologically acceptable solvate, hydrate or salt and/or hydrate thereof is present as the proton pump antagonist.

19. (Currently amended) ~~Dosage~~ The dosage form according to claim 9, comprising (7R,8R,9R)-2,3-dimethyl-8-hydroxy-7-(2-methoxyethoxy)-9-phenyl-7,8,9,10-tetrahydroimidazo[1,2-h][1,7]naphthyridine (INN soraprazan) or a pharmacologically acceptable solvate, hydrate or salt and/or hydrate thereof as the proton pump antagonist, sodium carbonate as the basic expient and microcrystalline cellulose, sodium carboxymethyl starch and magnesium stearate as the expipients.

20. (Currently amended) ~~Dosage~~ The dosage form according to claim 19, which is a film coated tablet.

21. (Currently amended) ~~Dosage~~ The dosage form according to claim 20, which comprises a ~~coloured~~ colored film coating.

22. (Currently amended) ~~Method~~ The method for preparing a dosage form according to claim 1 ~~one of the preceeding claims~~ comprising the step of thoroughly mixing the active ingredient with the basic excipient.

23. (Currently amended) ~~Rapidly~~ A rapidly disintegrating dosage form comprising an effective amount of a proton pump antagonist (APA), or a pharmacologically acceptable solvate, hydrate or salt thereof, together with one or more excipients which, on oral intake of the dosage form, ~~bring~~ brings about rapid disintegration of the dosage form, ~~and, optionally further excipients.~~

24. (Currently amended) ~~Dosage~~ The dosage form according to claim 23, which dosage form shows an immediate release of the proton pump antagonist (APA).

25. (Currently amended) ~~Dosage~~ The dosage form according to claim 24, which shows a disintegration time determined in water at 37°C of not more than 5 min and a release of active ingredient greater than or equal to 85% after 15 minutes in 0.1 N hydrochloric acid.

26. (Currently amended) ~~Dosage~~ The dosage form according to Claim 23, characterized in that (7R,8R,9R)-2,3-dimethyl-8-hydroxy-7-(2-methoxyethoxy)-9-phenyl-7,8,9,10-tetrahydroimidazo[1,2-h][1,7]naphthyridine (INN soraprazan) or a pharmacologically acceptable solvate, hydrate or salt and/or hydrate thereof is present as the proton pump antagonist.